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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,036	01/18/2006	Rino Antonio Bit	P33137USW	5914
23347	7590	12/18/2007	EXAMINER	
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B475 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			VALENROD, YEVGENY	
			ART UNIT	PAPER NUMBER
			1621	
			NOTIFICATION DATE	DELIVERY MODE
			12/18/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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JULIE.D.MCFALLS@GSK.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,036	<b>Applicant(s)</b> BIT ET AL.	
	<b>Examiner</b> Yevgeny Valenrod	<b>Art Unit</b> 1621	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 11-13, 17 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) 11-13, 17 and 19-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/06/07; 04/28/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-8 in the reply filed on 10/11/07 is acknowledged.

Claims 11-13, 17 and 19-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method of use and method of making, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/11/07.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims are directed to compounds of a provided formula and derivatives thereof. The term derivative(s) has not been defined in the specification. It is unclear which compounds are included and which are excluded by the term "derivative(s)". In order to advance the prosecution of the application examiner will interpret the term "derivative(s)" to represent compounds that have the same structural 3-ringcore that is common to all of the claimed compounds.

Claim 7 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the compounds of examples 1-90 in the specification. Structures and figures should be incorporated in claims. Examiner suggests listing the structures of compounds in examples 1-90.

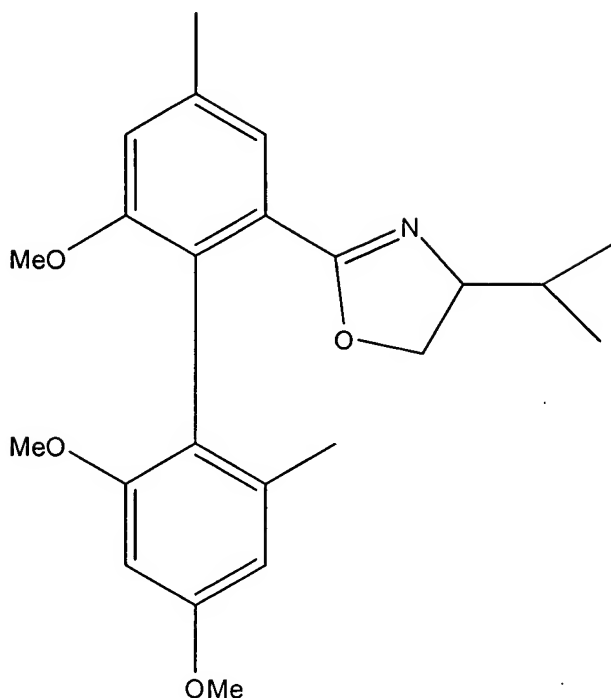
***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Baker et al (*Tetrahedron letters* **1999**, 40, 3475-3478). On page 3475, Baker et al disclose compound 4 (see structure below):

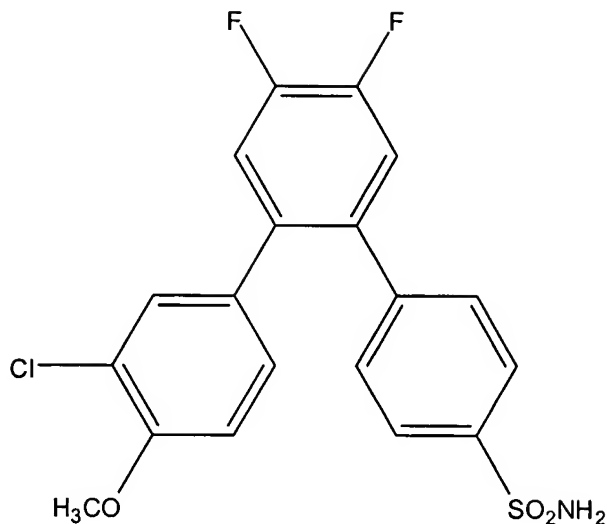


Compound 4 meets all the structural limitations of claim when:

Z-Rx = OMe; R2a = OMe; R2b = Me; A = 5-member heterocyclyl ring; R1 = alkyl; R8 = OMe and R9 = Me.

Claims 1-8 are rejected under 35 U.S.C. 102 (b) as being anticipated by Reitz et al. (WO 96/16934).

Reitz et al disclose compound of example 20 (p 85, structure below) and pharmaceutical composition comprising the said compound (pages 117-118)



The above compound is a derivative of the compounds claimed in the instant claims 1-7.

### ***Claim Rejections - 35 USC § 103***

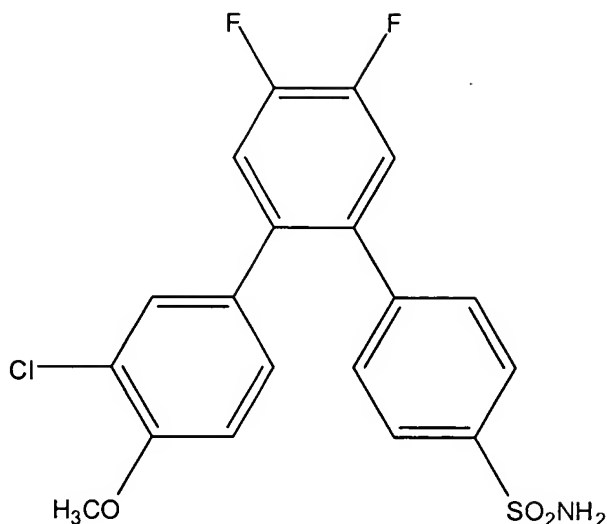
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reitz et al (WO 96/16934).

#### ***Scope of prior art***

Reitz et al disclose compound of example 20 (p 85, structure below) and pharmaceutical composition comprising the said compound (pages 117-118)



*Ascertaining the difference between prior art and instant claims*

The compound disclosed by Reitz et al. differs from the instantly claimed compounds in that the position of Z-Rx substituent in the instant claims is ortho, while it is para in the compound disclosed by Reitz. Also, the position of R1 group according to the instant claims is 1-2 or 1-3 with respect to the phenyl ring, while In Reitz it is positioned 1-4.

*Obviousness*

The difference between instant compounds and compound in Example 20 of Reitz et al is placement of substituents around a ring. "Compounds which differ only in the placement of substituents in a ring are not patentable absent unexpected results". In re Jones, 162 F.2d 638, 74 USPQ 152 (CCPA 1947).

***Double Patenting***

Claims 1-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 5 of copending Application No. 11/568573. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1-3 and 8 contain overlapping subject matter with claims 1-3 and 5 of '573. Instant claims 4-7 are obvious over the compound in claims 1-3 of '573. The difference between instant claim 4-7 and claims 1-3 of '573 is positioning of the ring substituents in the middle ring. "Compounds which differ only in the placement of substituents in a ring is not patentable absent unexpected results". In re Jones, 162 F.2d 638, 74 USPQ 152 (CCPA 1947).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Claims 1-8, 11-13, 17 and 19-21 are pending.

Claims 11-13, 17 and 19-21 are withdrawn

Claims 1-8 are rejected

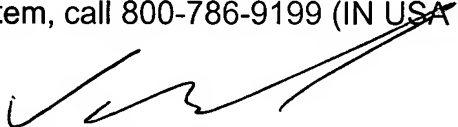
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

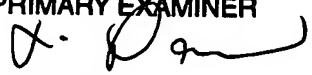
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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